REMARKS

Claims 1-51 were originally filed and were subject to election. In response to the Election Requirement, Applicants elected methods for diagnosing a renal disorder (as recited in claims 1-4, 7-12, 20-23, 26-35, 37-39, 42-44, and 47-49) and canceled claims 5, 6, 11, 12, 17, 18, 24, 25, 30, 31, and 36 without prejudice to their renewal. Claims 3, 4, 9, 10, 13-16, 19-23, 26-29, 33, 34, and 37-51 are canceled above without prejudice to their renewal. Claims 1, 2, 7, 8, 32, and 35 are currently pending.

Claims 1, 2, 7, 8, 32, and 35 are amended above. Support for amended claims 1 and 2 can be found at paragraph 0008 and in claims 3 and 4 as originally filed. Support for amended claims 7 and 8 can be found in claims 9 and 10 as originally filed. Support for amended claims 32 and 35 can be found in claims 33 and 34 as originally filed.

No new matter is added by any of the amendments.

RESPONSE

1. Rejection of claims 1-4, 7-10, 20-23, 26-29, 32-35, 37-39, 42-44, and 47-49 under 35 U.S.C. 112, 2nd paragraph

The Examiner rejected claims 1-4, 7-10, 20-23, 26-29, 32-35, 37-39, 42-44, and 47-49 under 35 U.S.C. 112, 2nd paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. Specifically, the Examiner indicated that claims 1, 7, 20, 26, 32, 37, 42, and 47, and claims dependent thereon, "are missing a contact step that would give an indication of how CTGF is detected in the subject sample." (Office Action, page 4.)

Claims 3, 4, 9, 10, 20-23, 26-29, 33, 34, 37-39, 42-44, and 47-49 are canceled above and the rejection is thus moot as to these claims. Claims 1, 7, and 32, as amended above, recite a contacting step. As amended claims 1, 7, and 32 recite a contacting step, as requested by the Examiner, the rejection of these claims, and of dependent claims 2, 8, and 35, is overcome, and Applicants respectfully request withdrawal of the rejection of these claims under 35 U.S.C. 112, 2nd paragraph.

2. Rejection of claims 1-4, 7-10, 20-23, 26-29, 32-35, 37-39, 42-44, and 47-49 under 35 U.S.C. 112, 1st paragraph

The Examiner rejected claims 1-4, 7-10, 20-23, 26-29, 32-35, 37-39, 42-44, and 47-49 under 35 U.S.C. 112, 1st paragraph, as failing to comply with the enablement requirement.

The Examiner stated that "Example 12 discloses the use of urine to detect CTGF for diagnosing the various renal disorders," but that there is "no guidance in the specification nor any example of any other patient sample that can be used in the instant invention other than urine." (Office Action, page 9.) Claims 1, 7, and 32 as amended above relate to methods of detecting a renal disorder using a urine sample. As claims 3, 4, 9, 10, 20-23, 26-29, 33, 34, 37-39, 42-44, and 47-49 are canceled herein, and claims 1, 7, and 32 as amended above are limited to use of a urine sample, this basis for the rejection is thus overcome.

The Examiner further stated that Nguyen et al. suggests that "the level of CTGF among patient samples correlates with severity of renal disease, rather than presence[,] since control levels overlapped with patient samples ...." (Office Action, page 8.) The Examiner concludes that "the art shows that using CTGF to diagnose any single renal disorder is unpredictable, much less all of the recited renal diseases and pathologies." (Office Action, page 9.)

Applicants respectfully disagree. Regarding the Examiner's statement that "using CTGF to diagnose any renal disorder is unpredictable," Applicants note that, first, the claims as currently amended do not recite "any ... renal disorder," but are limited to recitation of renal disorders associated with diabetes, hyperglycemia, and increased levels of glucose. Second, Nguyen et al. states that, despite overlap between patient and control groups in the Nguyen studies, "[a] significant difference in U-CTGF was observed ... between patients with diabetic nephropathy and healthy control subjects," and concludes that "U-CTGF is significantly increased in diabetic nephropathy." (Nguyen et al., pages 84-85 and page 86, respectively.) Therefore, Nguyen, published after the filing date of the above-referenced application, validates the invention as described in the present claims, that an increased level of CTGF protein in a urine sample is indicative of the presence of a renal disorder associated with, e.g., diabetes. For at least these reasons, Applicants submit that pending claims 1, 2, 7, 8, 32, and 35 are fully enabled, and withdrawal of this basis for the rejection is respectfully requested.

In summary, claims are 1, 2, 7, 8, 32, and 35 are fully enabled for at least the reasons provided above. Claims 3, 4, 9, 10, 20-23, 26-29, 33, 34, 37-39, 42-44, and 47-49 are canceled above and the rejection is thus moot as to these claims. Accordingly, withdrawal of the rejection of these claims under 35 U.S.C. 112, 1st paragraph, as failing to comply with the enablement requirement, is thus respectfully requested.

Also, the Examiner noted that U.S. Provisional Patent Application Nos. 60/099,471 and 60/112,855 disclose that 4 of the 8 patients were diabetic, but the instant application states that 3 of the 8 patients were diabetic. The Examiner requested clarification. The correct number is 3. The specifications of U.S. Provisional Patent Application Nos. 60/099,471 and 60/112, 855 erroneously stated "4," but this was corrected to read "3" in the instant specification as filed. That the correct number is 3 is evidenced, for example, by the immunoblot blot presented in Figure 18 in the present application, corresponding to Figure 13 in U.S. Provisional Patent Application No.60/112,855, which contains 3 lanes labeled D, each corresponding to samples obtained from a diabetic patient.

3. Rejection of claims 1-4, 7-10, 20-23, 26-29, 32-35, 37-39, 42-44, and 47-49 under 35 U.S.C. 112, 1st paragraph

The Examiner rejected claims 1-4, 7-10, 20-23, 26-29, 32-35, 37-39, 42-44, and 47-49 under 35 U.S.C. 112, 1st paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The Examiner stated that "[t]he 'sample' genus recited in the claims encompasses many samples that were not described in the specification to such a degree that one of ordinary skill in the art would know what samples can be used in the instant invention other than a urine sample."
(Office Action, pages 12-13.)

Applicants appreciate the Examiner's statement that the Applicant "is in possession of: a method of diagnosing a renal disorder in a subject having diabetes comprising obtaining a urine sample...," etc. (Office Action, page 10.) The Examiner further stated that "samples ... were not described in the specification to such a degree that one of ordinary skill in the art would know what samples can be used in the instant invention other than a urine sample." (Office Action, page 13.) Accordingly, independent claims 1, 7, and 32 are amended above to recite a "urine sample," and are thus free of this basis for the rejection. Claims 2, 8, and 35 depend therefrom, and are thus also free of this basis for the rejection. Claims 3, 4, 9, 10, 20-23, 26-29, 33, 34, 37-39, 42-44, and 47-49 are canceled above and the rejection is thus moot as to these claims. Accordingly, Applicants respectfully request withdrawal of the rejection of claims 1, 7 and 32, and their dependent claims 2, 8, and 35, respectively, under 35 U.S.C. 112, 1st paragraph, for lack of written description.

4. Rejection of claims 1-2, 4, 7-8, 10, 20-21, 23, 26-27, 29, 32, 34-35, 37, and 39 under 35 U.S.C. 102
The Examiner rejected claims 1-2, 4, 7-8, 10, 20-21, 23, 26-27, 29, 32, 34-35, 37, and 39 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,232,064.

Claims 4, 10, 20-21, 23, 26-27, 29, 34, 37, and 39, are canceled above and the rejection is thus moot as to these claims.

The Examiner stated that the '064 patent teaches various methods for diagnosing a renal disorder. In particular, the Examiner stated that the '064 patent

> "teaches... [a] method for diagnosing a renal disorder associated with increased glucose (kidney fibrosis)...," [a] method for diagnosing a renal disorder in a subject having hyperglycemia (kidney fibrosis)...," and "[a] method for diagnosing a renal disorder in a subject having diabetes (kidney fibrosis), the method comprising: (a) obtaining a sample from the subject; (b) detecting the level of CTGF protein in the sample; and (c) comparing the level of CTGF protein in the sample to a standard level of CTGF protein, wherein an increased level of CTGF protein is indicative of the presence of the renal disorder...." (Office Action, pages 15-16.)

Applicants submit that the '064 patent relates generally to diagnosing pathological states in a subject suspected of having pathology characterized by a cell proliferative disorder. The '064 patent does not disclose methods as recited in instant claims 1, 7, and 32, directed to methods for diagnosing a renal disorder in "a subject having increased levels of glucose," "in a subject having hyperglycemia," or "in a subject having diabetes," respectively. Additionally, the '064 patent does not disclose methods for diagnosing a renal disorder in the above-identified subjects by detecting the level of CTGF protein in a urine sample, as recited in claims 1, 7, and 32.

Therefore, the '064 patent fails to disclose the methods recited in claims 1, 7, and 32, and their dependent claims 2, 8 and 35. Thus, the '064 patent fails to anticipate claims 1, 2, 7, 8, 32, and 35, and Applicants respectfully request withdrawal of the rejection of these claims under this section.

5. Rejection of claims 3, 9, 22, 28, 33, 38, 42-44, and 47-49 under 35 U.S.C. 103

The Examiner rejected claims 3, 9, 22, 28, 33, 38, 42-44, and 47-49 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,232,064 in view of U.S. Patent No. 5,753,517.

Claims 3, 9, 22, 28, 33, 38, 42-44, and 47-49 are canceled above and the rejection is thus moot as to these claims. Accordingly, Applicants respectfully request withdrawal of this rejection.

6. Rejection of claims 1-2, 7-8, 20-21, 26-27, 32, 35, and 37 under 35 U.S.C. 103

The Examiner rejected claims 1-2, 7-8, 20-21, 26-27, 32, 35, and 37 under 35 U.S.C. 103(a) as being unpatentable over Ito et al. in view of Gygi et al.

Claims 20-21, 26, 27, and 37 are canceled above and the rejection is thus moot as to these claims.

The Examiner stated that Ito et al.

> "teaches... [a] method for diagnosing a renal disorder associated with increased glucose in a subject (diabetic nephropathy)...," [a] method for diagnosing a renal disorder in a subject having hyperglycemia (diabetic nephropathy)...," and "[a] method for diagnosing a renal disorder in a subject having diabetes (diabetic nephropathy), the method comprising: (a) obtaining a sample (kidney specimen) from the subject; (b) detecting the level of CTGF protein (mRNA) in the sample; and (c) comparing the level of CTGF protein (mRNA) in the sample to a standard level of CTGF protein (mRNA), wherein an increased level of CTGF protein (mRNA) is indicative of the presence of the renal disorder...." (Office Action, pages 19-20.)

Applicants submit that Ito et al. describes the expression of CTGF mRNA in human kidney biopsy specimens to assess the correlation between interstitial CTGF mRNA expression and chronic tubulointerstitial injury. Ito et al. does not teach or suggest a method for "diagnosing a renal disorder... [by] detecting the level of CTGF protein" as recited in instant claims 1, 2, 7, 8, 32, and 35. Additionally, Ito et al. does not teach or suggest a method for diagnosing a renal disorder by detecting the level of CTGF protein in a "urine sample" as recited in the instant claims.

The deficiencies in the teachings of Ito et al. are not remedied by Gygi et al. The Examiner stated that one of ordinary skill in the art "would have been motivated to measure protein as taught by Gygi et al. in the CTGF detection methods of Ito et al. because Gygi et al. teaches that mRNA expression levels are not a good indication of CTGF protein expression levels." (Office Action, page 21.) Gygi et al. examined the relationship between yeast mRNA levels and yeast protein expression levels for selected genes expressed in *Sacccharomyces cerevisiae*. Ito et al. examined CTGF mRNA expression in kidney biopsy samples. Applicants submit that neither Gygi et al. nor Ito et al. teach or suggest a method of diagnosing a renal disorder by detecting the level of "CTGF protein" in a "urine sample," as recited in the instant claims. As neither of these references, alone or in combination, teach or suggest the methods recited in claims 1, 2, 7, 8, 32, and 35 in the instant application, Applicants respectfully request that the rejection of these claims under 35 U.S.C. 103(a) as being unpatentable over Ito et al. in view of Gygi et al. be withdrawn.

CONCLUSION

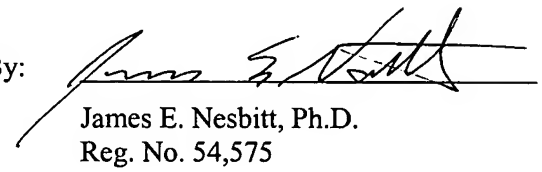
In view of the foregoing, Applicants submit that the claims are fully in condition for allowance and request notification to that effect.

The Commissioner is hereby authorized to charge the total of any fee necessary in this communication to Deposit Account No. 50-0811, referencing Docket No. FP0806.1 CON. This response is enclosed in duplicate.

Please call Applicants' representative at 650-866-7289 with any questions regarding the present communication or the above-referenced application.

Respectfully submitted,

Date: 15 November 2007

By: 

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